

# **EXHIBIT 27**

agnosis of asbestos-related disease. It is important for the physician diagnosing asbestosis not to rely on chest radiographs alone, and in fact the Association of Occupational and Environmental Clinics has stated that such an act is unethical (5). There are additional and medically necessary steps to reach a diagnosis of asbestosis. However, we cannot support the conclusions of Gitlin and colleagues' study because of the potential bias in the selection of the study sample, the potential bias on the part of the consultant readers, and the clear high rate of variability among the consultant readers.

#### Authors' disclosure statement:

The authors of this letter have done medical-legal work in the area of asbestos-related disease in the form of medical reports and testimony for patients seen in their clinical practice, and in some cases for individuals not examined. The major portion of this work has been for plaintiffs' attorneys. For this work we have received consultation fees. Our research in the area of asbestos-related disease has not been funded by attorneys, nor have other relevant activities, such as testimony before the U.S. Congress or the drafting of published guidelines for the diagnosis and treatment of asbestosis.

#### REFERENCES

1. Gitlin JN, Cook LL, Linton OW, and Garrett-Mayer E. Comparison of "B" readers' interpretations of chest radiographs for asbestos related changes. *Acad Radiol* 2004; 11(8):843-856.
2. Landis JR, Koch GG. The measurement of observer agreement for categorical data. *Biometrics* 1977; 33:159-174.
3. Welch LS, Hunting KI, Schiffman A, Balmes J, Bresnitz E, Guidotti T, Lockett J, Mahale W, and Myo-Lwin T. Variability in the classification of pneumoconioses using the 1980 International Labor Organization classification system for pneumoconioses. *Chest* 1998; 114: 1740-1748.
4. American Thoracic Society. Diagnosis and Initial management of nonmalignant diseases related to asbestos. *Am J Respir Crit Care Med* 2004; 160:691-715.
5. The Association of Occupational and Environmental Clinics Policy Statement on Asbestos Screening, 2000. <http://www.aoc.org/asbestos-screen.htm>

#### From:

Alan M. Ducatman MD, MS  
Professor and Chair  
Department of Community &  
University School of Medicine  
Morgantown, WV

#### To The Editor:

Gitlin and colleagues have revisited the problem of variability in the interpretation of radiographs obtained for the purpose of detecting asbestos-related abnormalities (1). The problem that they address has persisted for too long, and is worth re-examining so long as it persists.

The documented findings are expected. First, the authors used a methodology that is not designed to understate the problem, beginning with films interpreted by B readers retained by plaintiffs' attorneys. Second, very substantial differences in reader behavior were inferred between readers in our much larger study two decades ago. This earlier study was not conducted in the context of legal proceedings, and relied on very large numbers of randomly distributed packets of radiographs obtained on behalf of the U.S. Navy (and its substantial industrial operations, including shipyards). Despite the large numbers of films for each reader and the absence of a legal setting, it was clear that epidemics could appear and disappear depending on the choice of reader (2).

The impact of B-reader behavior was substantial then, and not unidirectional. For 23 high-volume B-readers, Navy data abnormalities  $\geq 1/0$  ranged from 0.05% to 10.93% (median: 1.71%), and from 0.02% to 7.55% for  $\geq 1/1$ , encompassing several orders of magnitude (4). While "over-reading" is emphasized in the article by Gitlin and colleagues and the accompanying editorial by Janower and Berlin (3), the failure to find existing disease is generally regarded as the most serious problem in medical surveillance efforts. Because the normative film in most samples will be normal, an "over-reader" may appear more culpable than an "under-reader" in the types of statistical analyses that both we and Gitlin and colleagues applied. Both over-reading and under-reading are important problems; deciding which is the more culpable error is a matter of perspective. Quality assurance is a good for the goose as well as for the gander.

It has been clear for two decades that the social utility of the B-reading program as currently configured is problematic. The assertion that the International Labour Office system was "designed for research" is merely a failure to address the social problem. That failure in turn affects the health beliefs of our patients. The B-reading process is also referred to in U.S. Occupational Safety and Health Administration law (1910.1001). It is time to stop pretending that the testing examination alone provides sufficient quality assurance to address the needs of exposed populations. The solution attributed to me by Gitlin and colleagues (1), of multiple readings, is likely to be an

## LETTERS TO THE EDITOR

Academic Radiology, Vol 11, No 12, December 2004

improvement; if used alone, however, it will lead to under-reading, for several statistical reasons. The substantial differences among the expert panel for positive films in the article by Gitlin and colleagues illustrate one aspect of the problem. Requiring positive agreement among multiple readers is no more logical than the same requirement for negative agreement: without additional quality assurance, such a step would be insufficient and punitive. If the goal is to standardize readings, several approaches could improve quality assurance. Ultimately, all of these approaches amount to a concerted effort to reduce the number of readers to a group that will read similarly. An "asbestos board," with experts who undergo ongoing quality assurance testing and are also retained for continued normative behavior and dropped for non-normative behavior, is probably the simplest approach (4). There is no "gold standard," but we can achieve consistency. The barriers are political, not statistical.

Because the mixed messages from certified interpreters affect our patients' health beliefs, and because health beliefs affect behavior at many levels, the data presented are sufficient justification for considering the current system. The goal is not to choose a winning side—taking sides is part of what has gotten us to where we are today. Rather, the goal is to provide quality assurance. Some means to ensure consistent behavior, most likely in a small number of readers who undergo continual, random, voluntary quality assurance testing processes, is the socially useful solution. Getting there will require a "C-reading" from a planning committee that demonstrates competence, compassion, courage, and compromise.

## Author's disclosure

Dr. Ducatman is not a B-reader and does not receive personal payment for testifying concerning his patients. Dr. Ducatman is an internist and occupational physician, and some of his patients are seen for reasons related to asbestos exposure. He has been queried, by either plaintiffs' or defense attorneys, concerning clinical findings and epidemiologic aspects of asbestos exposure, including quality assurance.

## REFERENCES

- Gitlin JN, Cook LL, Linton OW, and Garrett-Mayer E. Comparison of "B" readers' interpretations of chest radiographs for asbestos-related changes. *Acad Radiol* 2004; 11:843-858.
- Ducatman AM, Yang WN, and Forman SA. "B" readers and asbestos medical surveillance: radiographic interpretation of asbestosis. *J Occup Med* 1988; 30:544-547.

3. Janower ML, and Berlin L. "B" readers' radiographic interpretations in asbestos litigation: is something rotten in the courtroom? *Acad Radiol* 2004; 11:841-842.
4. Ducatman AM. Variability in the interpretation of radiographs for asbestosis abnormalities: problems and solutions. *Ann NY Acad Sci* 1991; 643:108-121.

## From:

Alfred Franzblau, MD  
Professor of Occupational Medicine

Brenda Gillespie, PhD  
Assistant Professor of Biostatistics  
Research Scientist  
Center for Statistical Consultation and Research  
University of Michigan School of Public Health

## To the Editor:

The stated purpose of the article by Gitlin et al (1) on comparing B readers' interpretations of chest radiographs for asbestos-related changes was "to determine if chest radiographic interpretations by physicians retained by attorneys representing persons alleging respiratory changes from occupational exposure to asbestos would be confirmed by independent consultant readers." This is an important objective scientifically and for public policy, and has major legal ramifications. However, because of potential flaws in the design, execution, and analyses of Gitlin and colleagues' study, that were ambiguously reported in their article, the study objective may not have been achieved.

An essential element in the design of this type of study is the process by which films are selected for inclusion in the study. In order for the results to be interpretable and generalizable, films entered into the study must be randomly selected and therefore likely to be representative of the distribution of all similar films, and thus free of bias. In the article by Gitlin et al., the film selection process is described as follows: "Seven groups of films and initial reports, totaling 551 cases, were made available to the authors from several legal sources. The authors were not given the names of the plaintiffs' law firms nor was demographic material provided about the individuals who were examined."

Gitlin and colleagues' article carries no description of the film-selection process used in their study, and it would appear that the authors have no knowledge of this process, since they did not select the films. We are not